

**510(k) Summary of Safety & Effectiveness**

SEP - 6 2005

**Submitter** Vanguard Medical Concepts, Inc.  
5307 Great Oak Drive  
Lakeland, FL 33815

**Contact** Heather Crawford, RAC  
Director of Regulatory Affairs  
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**Date** June 16, 2005

- Device**
- Trade Name: Vanguard Reprocessed External Fixation Devices
    - EBI DFS Standard Fixator
    - EBI DFS Small Fixator
    - EBI DFS Distal Radius Fixator
    - EBI DES Hybrid Fixator
  - Common Name: Reprocessed External Fixation Devices
  - Classification: 21 CFR 888.3030
  - Classification Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
  - Product Code: KTT – Class II

**Predicate Devices** External Fixation Devices legally marketed by the following original equipment manufacturer:

Manufacturer	Trade Name
EBI® Medical Systems, Inc.	DFS® Standard Fixator
EBI® Medical Systems, Inc.	DFS® Small Fixator
EBI® Medical Systems, Inc.	DFS® Distal Radius Fixator
EBI® Medical Systems, Inc.	DFS® Hybrid Fixator

**Indications for Use** Reprocessed External Fixation Devices are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

- Contra-indications**
- External fixation devices are contraindicated in patients with mental or neurologic impairment that would interfere with cooperative postoperative care.
  - These devices are not intended for attachment or fixation of screws to the spine.

## 510(k) Summary of Safety & Effectiveness, continued

### Device Description

Vanguard Reprocessed External Fixation Devices are previously used non-invasive orthopedic devices that have been cleaned, inspected, tested, and packaged by Vanguard Medical Concepts, Inc. External fixation device systems are comprised of various elements that, when used in conjunction with one another, form bridge constructs to which anchoring screws, wires and/or pins may be attached. Bridge elements are designed to provide a framework for stabilization of bone fractures where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casting or other means of internal fixation.

External fixation elements consist of components such as rails and modular rails, rail-to-rail couplings, rail-to-screw clamps, rail-to-clamp couplings, rail-to-clamp couplings, and clamp-to-clamp couplings. These components are provided in bulk, packaged in nylon pouches, non-sterile, with instructions for steam sterilization by the health care facility.

- **Rods, Rails and Modular Rails** ~ Straight rods and rails are external fixation devices of varying lengths (adjustable in the case of modular rods and rails) and dimensions that are used with rail-to-rail, rod-to-rail, rod/rail-to-ring, and rail-to-screw clamps by the surgeon to connect anchoring pins and screws together to form a rigid structure that immobilizes the affected bone or structures. Differences in the dimensions of the rods and rails allow accommodation of a broad range of fracture scenarios and applied loads. All rods and rails have a straight, solid design. These devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.
- **Rings and Ring Segments** ~ Rings and ring segments are circular or semicircular segments manufactured to surround the area of attachment to bone located centrally in the ring. Various attachments are made to the rings or ring segments to stabilize bone fractures or to reduce or extend the length of bones. Tensioned wires or pins are commonly attached to rings and ring segments using clamps designed for this purpose. Multiple ring or ring segment constructs are used to stabilize and structurally support the anatomical structures being treated using a range of configurations and attachments and connectors. The rings and ring segments are manufactured in a range of diameters to allow selection of a size most appropriate to the anatomy and application needed. Rings and ring segments are typically manufactured from one or more of the following materials: anodized aluminum alloys, steel and stainless steel alloys or carbon fiber composites.

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## 510(k) Summary of Safety & Effectiveness, continued

### Device Description (continued)

- **Ring-to-Rod/Rail Clamps** ~ Ring-to-rod/rail clamps are utilized to connect a ring or ring segment to a rod/rail. These attachments are made to form an external fixator frame construct as required for the particular biomechanical needs of the procedure. Ring-to-rod/rail clamps are typically constructed from one or more of the following materials: anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.
- **Ring-to-Pin or Ring-to-Wire Clamps** ~ Ring-to-pin or ring-to-wire clamps are utilized to connect an external fixation ring or ring segment to a pin or wire that is normally attached on one side of the ring, passed through the bone, and continue to an attachment point on the opposite side of the ring where they are affixed under tension to another ring to wire clamp. Ring-to-pin or wire clamps are used to secure the ring to a pin, wire or set of pins and wires that are anchored in the bone passing centrally through the external fixation ring. Ring-to-pin and ring-to-wire clamps are typically constructed from one or more of the following materials: anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.
- **Rod/Rail-to-Screw Clamps** ~ Rod/Rail-to-screw clamps are utilized to connect an external fixation rail to a pin that is normally affixed to the bone. Rod/Rail-to-screw clamps are used to secure the rod/rail to a screw or set of screws that are anchored in the bone.

DFS System rod/rail-to-screw clamps are V-shaped to provide tri-planar compression on bone screws. Distraction components are affixed to certain models of DFS Distal Radius Fixator rod/rail-to-screw clamps to provide distraction capabilities on the distal fixator rail. The devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.

- **Rail-to-Rail Couplings** ~ Rail-to-Rail couplings are multi-element components used to connect one rail to another in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rails. These devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.
- **Rod-to-Rail Couplings** ~ Rod-to-Rail couplings are multi-element components used to connect one rod to a rail in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or a range of sizes of rods and rails. These devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.

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## 510(k) Summary of Safety & Effectiveness, continued

### Device Description (continued)

- **Rod-to-Rod Couplings** ~ Rod-to-Rod couplings are multi-element components used to connect one rod to another in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods. The devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.
- **Rail-to-Clamp Couplings** ~ Rail-to-clamp couplings are multi-element components used to connect one rail to a clamp in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rails. The devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.
- **Rod-to-Clamp Couplings** ~ Rod-to-clamp couplings are multi-element components used to connect one rod to a clamp in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods. The devices are typically constructed from one or more of the following materials: anodized aluminum and stainless steel.
- **Clamp-to-Clamp Couplings** ~ Clamp-to-clamp couplings are multi-element components used to connect one clamp to another in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of clamps. The devices are typically constructed from one or more of the following materials: anodized aluminum or stainless steel.

### Technological Characteristics

Vanguard Reprocessed External Fixation Devices are essentially identical to the Original Equipment Manufacturer (OEM) devices. No changes are made to the currently marketed OEM device specifications and the Reprocessed External Fixation Devices possess identical technological characteristics.

### Test Data

Cleaning, packaging, and performance testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

### Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed External Fixation Devices are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.



SEP - 6 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Heather Crawford, RAC  
Director of Regulatory Affairs  
Vanguard Medical Concepts, Inc.  
5307 Great Oak Drive  
Lakeland, Florida 33815

Re: K051616

Trade/Device Name: Vanguard Reprocessed External Fixation Devices (see attached list)

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation  
appliances and accessories

Regulatory Class: II

Product Codes: KTT, LXT

Dated: June 16, 2005

Received: June 17, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

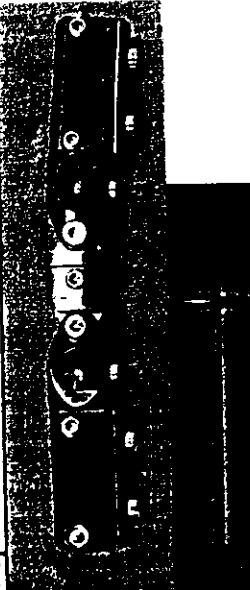
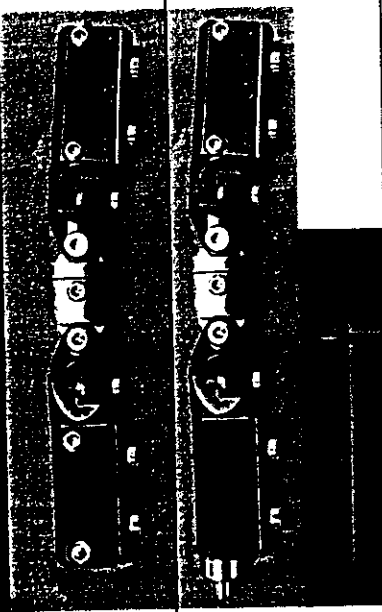
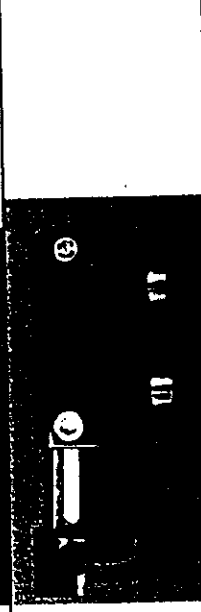
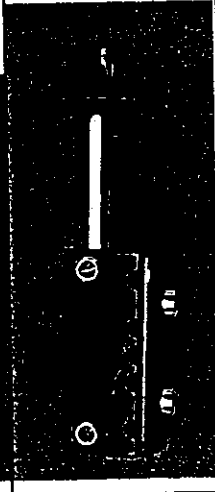

Sincerely yours,


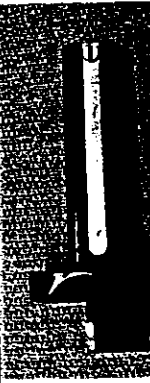









for Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



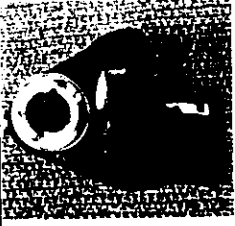
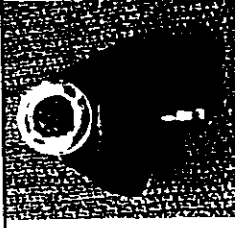



Enclosure

## DynaFix DFS Standard Fixator

Catalog #	Description	Representative Image	Mat.(s)
01000	DFS Standard Fixator Includes: DFS Std Fixator (01001), Modular C/D Mechanism 0-5cm (01150), End Cap (01175), 5mm Allen Wrench (03110)		Anodized Aluminum, Stainless Steel
01001	DFS Standard Fixator Includes: DFS Central Body (01110), L Telescoping Arm Complete 0-5cm (01010), R Telescoping Arm Complete 0-5cm (01020)		Anodized Aluminum, Stainless Steel
01005	Standard Fixator Complete - 5mm Allen Wrench (03110), C/D Mechanism 0-5cm (01150), End Cap (01175), Dynamization Component 0-5cm (01160)		Anodized Aluminum, Stainless Steel
01010	L Telescoping Arm Complete 0-5cm		Anodized Aluminum, Stainless Steel
01030	L Telescoping Arm 0-8cm		
01020	R Telescoping Arm Complete 0-5cm		Anodized Aluminum, Stainless Steel
01040	R Telescoping Arm 0-8cm		
01045	L Male Stem 0-5cm		Anodized Aluminum,

Catalog #	Description	Representative Image	Mat.(s)
01055	L Male Stem 0-8cm		Stainless Steel
01050	R Male Stem 0-5cm		Anodized Aluminum, Stainless Steel
01060	R Male Stem 0-8cm		Anodized Aluminum, Stainless Steel
01070	Female Clamp Complete 0-5cm		Anodized Aluminum, Stainless Steel
01100	Female Clamp Complete 0-8cm		Anodized Aluminum, Stainless Steel
01075	Female Clamp Base 0-5cm		Anodized Aluminum, Stainless Steel
01105	Female Clamp Base 0-8cm		Anodized Aluminum
01080	Clamp Cover		Anodized Aluminum
01090	Locking Screw Set		Stainless Steel

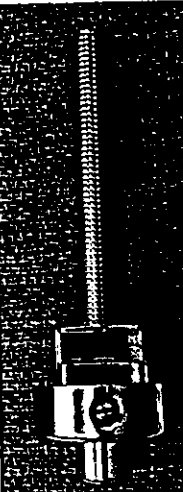

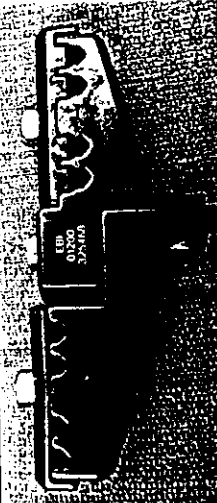
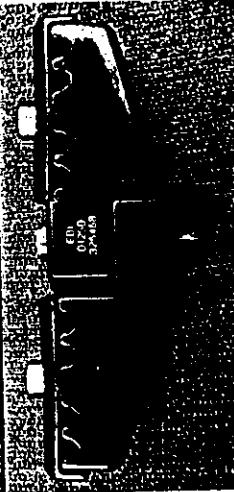



Catalog #	Description	Representative Image	Mat.(s)
01175	End Cap		Anodized Aluminum
01110	DFS Central Body Component Includes: Inner Body Female Rotation Component (01130), Inner Body Male Rotation Component (01135), Left Dual Locking Connector (01120), Right Dual Locking Connector (01115)		Anodized Aluminum, Stainless Steel
01115	Right Dual Locking Connector		Anodized Aluminum, Stainless Steel
01120	Left Dual Locking Connector		Anodized Aluminum, Stainless Steel
01145	Inner Body Rotation Component Kit Includes: Inner Body Female Rotation Component (01130), Inner Body Male Rotation Component (01135)		Anodized Aluminum, Stainless Steel
01130	Inner Body Female Rotation Component	Female End (01130)	Male End (01135)
01135	Inner Body Male Rotation Component	Inner Body Rotation Complete	
01140	Locking Connector Bolt (pack of 4)		Stainless Steel
01160	Dynamization Component 0-5cm		Stainless Steel
01165	Dynamization Component 0-8cm		

PS4340: Appendix A: External Fixation Devices – EBI DynaFix™ DFS™ Standard Fixator

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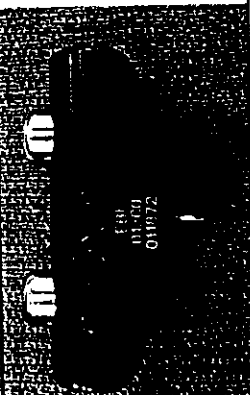


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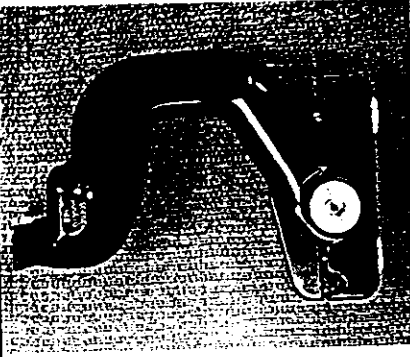
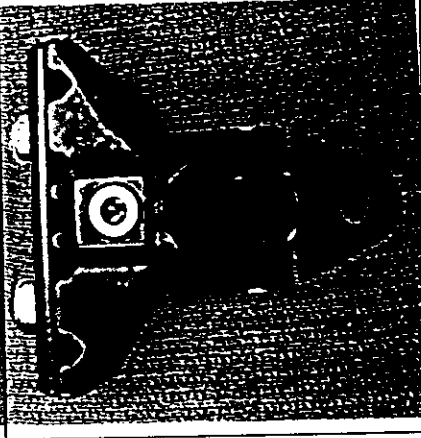
Catalog #	Description	Representative Image	Mat.(s)
01180	Modular C/D Mechanism 0-5cm		Stainless Steel
01185	Modular C/D Mechanism 0-8cm		
01430	Enhanced Access C/D Mechanism 0-5cm		Stainless Steel, Anodized Aluminum
01435	Enhanced Access C/D Mechanism 0-8cm		
03140	Wrench for 01430 and 01435 Enhanced Access C/Ds	NO PHOTO AVAILABLE	Stainless Steel
01200	DFS Convergent T-Clamp Offset Includes: Left Clamp Body (1255), Parallel Clamp Cover (1270), Offset Clamp Body (1260), Clamp Cover Locking Bolt (01085)		Anodized Aluminum, Stainless Steel
01250	DFS Convergent T-Clamp Parallel Includes: Parallel Clamp Body (01265), Parallel Clamp Cover (01270), Clamp Cover Bolt (01085)		Anodized Aluminum, Stainless Steel
01255	Left Clamp Body		Anodized Aluminum, Stainless Steel

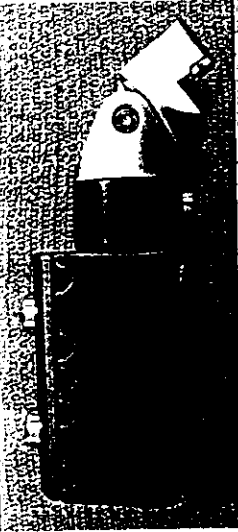
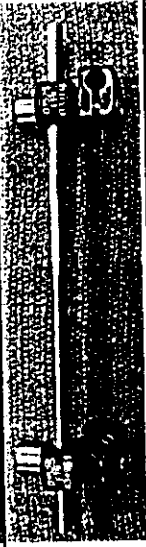

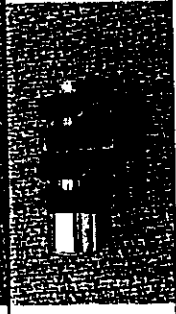
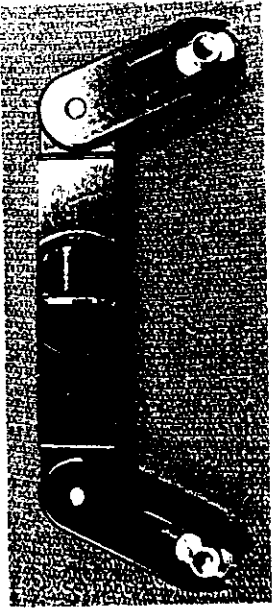
PS4340: Appendix A: External Fixation Devices – EBI DynaFix™ DFS™ Standard Fixator

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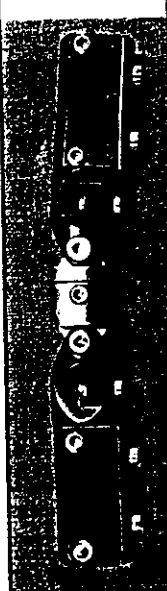

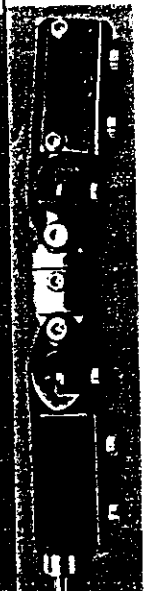
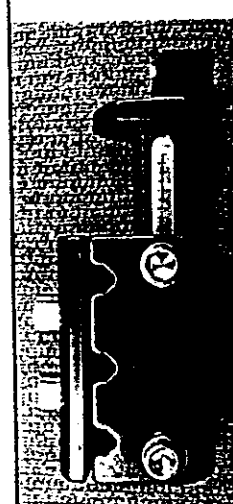
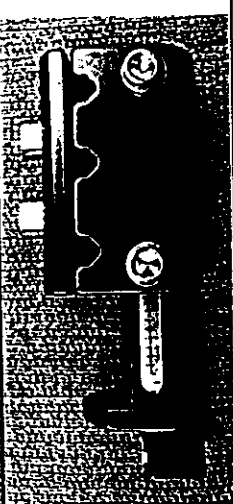
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Catalog #	Description	Representative Image	Mat.(s)
01260	Offset Clamp Body		Anodized Aluminum, Stainless Steel
01265	Parallel Clamp Body	AS ABOVE BUT WITH SHALLOW SLOTS	Anodized Aluminum, Stainless Steel
01270	Parallel Clamp Cover		Anodized Aluminum
01275	Offset Clamp Cover		Anodized Aluminum
01300	DFS T-Clamp Complete Includes: T-Clamp Body (01305), Clamp Cover (01080), T-Clamp Body (01085)		Anodized Aluminum, Stainless Steel
01305	T-Clamp Body		Anodized Aluminum, Stainless Steel
01080	Clamp Cover		Anodized Aluminum

Catalog #	Description	Representative Image	Mat.(s)
01085	Clamp Cover Locking Bolt		Stainless Steel
01350	DFS Ankle Clamp		Anodized Aluminum, Stainless Steel
01400	DFS Angular Hinge Clamp		Anodized Aluminum, Stainless Steel
01450	Pivot Body with T-Clamp	SIMILAR TO ABOVE BUT ONLY SINGLE AXIS OF ROTATION	Anodized Aluminum, Stainless Steel

Catalog #	Description	Representative Image	Mat.(s)
01460	Pivot Body with Straight Clamp		Anodized Aluminum, Stainless Steel
01500	DFS Standard Fixator Supplemental Bone Screw Clamp Includes: 150mm Rod (01515), Individual Bone Screw Clamps (01525)		Anodized Aluminum, Stainless Steel
01515	Supplemental Rod 150mm		Stainless Steel
01520	Supplemental Rod 300mm		
01525	Individual Bone Screw Clamp		Anodized Aluminum, Stainless Steel
01700	Universal Ring Adapter-Style B, Includes Adapter Clamp, Style A and B Bolt Sets		Anodized Aluminum, Stainless Steel
01705	Universal Ring Adapter-Style A, Includes Adapter Clamp, Spacers (3), Style A Bolt Set		Anodized Aluminum, Stainless Steel
01710	Universal Ring Adapter Clamp Spacers (3)		Anodized Aluminum
01735	Adapter Clamp Bolt Set – Style A Used with Drilled Ring		Stainless Steel
01740	Adapter Clamp Bolt Set – Style B Used with Solid Ring		Stainless Steel


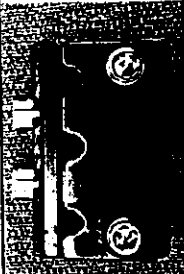




### DynaFix DFS Small Fixator


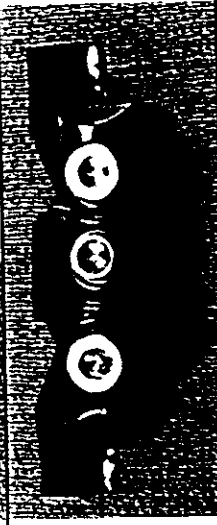



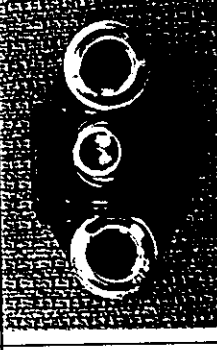

02000	DFS Small Fixator Complete – Includes: DFS Small Fixator (02001), C/D Mechanism 0-5mm (02148), Small End Cap (02175), 5mm Allen Wrench (03110)		Anodized Aluminum, Stainless Steel
02001	DFS Small Fixator – Includes: Small Central Body Component Complete (02110), Small L Telescoping Arm 0-3cm (02010), Small R Telescoping Arm 0-3cm (02020)		
02005	DFS Small Fixator Complete with Dynamization Component – Includes: C/D Mechanism 0-3cm (02180), Dynamization Component 0-3cm (02155), Small End Cap (02175), 5mm Allen Wrench (03110)		
02010	DFS Small L Telescoping Arm (0-3cm) Complete Includes: 02050, 02030		Anodized Aluminum, Stainless Steel
02025	DFS Small L Telescoping Arm (0-5cm) Complete Includes:		
02020	DFS Small R Telescoping Arm (0-3cm) Complete Includes: 02055, 02040		
02026	DFS Small R Telescoping Arm (0-5cm) Complete Includes:		Anodized Aluminum, Stainless Steel
02030	DFS Small L Male Stem (0-3cm)		
02045	DFS Small L Male Stem (0-5cm)		

PS4340: Appendix A: External Fixation Devices – EBI DynaFix™ DFS™ Standard Fixator

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02040	DFS Small R Male Stem (0-3cm)		
02046	DFS Small R Male Stem (0-5cm)		
02050	Small L Female Clamp Complete (0-3cm) Includes:		Anodized Aluminum, Stainless Steel
02055	Small R Female Clamp Complete (0-3cm) Includes:		Anodized Aluminum, Stainless Steel
02060	Small L Clamp Base (0-3cm)		Anodized Aluminum
02065	Small R Clamp Base (0-3cm)		
02078	Small Clamp Cover (0-3cm)		
02070	Small Female Clamp Complete (0-5cm) Includes:	PHOTO SIMILAR TO 2050 BUT LONGER (AMBIDEXTROUS)	Anodized Aluminum, Stainless Steel
02075	Small Female Clamp Base (0-5cm)	PHOTO SIMILAR TO 2060 BUT LONGER (AMBIDEXTROUS)	Anodized Aluminum, Stainless Steel
02080	Small Clamp Cover (0-5cm)	PHOTO SIMILAR TO 2078 BUT LONGER	Anodized Aluminum Stainless Steel
02085	Small Clamp Cover Locking Bolt		
02090	Small Locking Set Screw		Stainless Steel

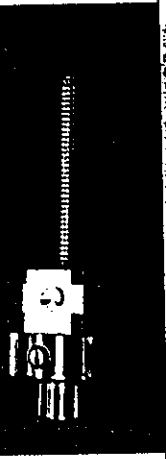
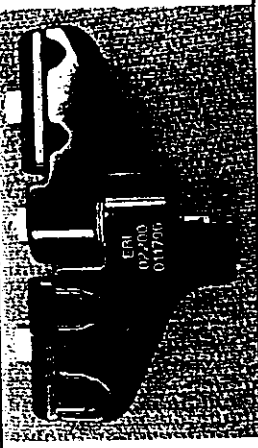

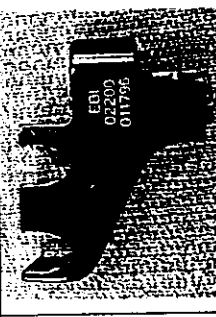

02175	Small End Cap		Anodized Aluminum
02110	DFS Small Central Body Component Complete Includes: 02130, 02135, 02120, 02115		Anodized Aluminum, Stainless Steel
02115	Small R Dual Locking Connector Component		Anodized Aluminum, Stainless Steel
02120	Small L Dual Locking Connector Component		
02130	Small Inner Body Female Rotational Component		Anodized Aluminum, Stainless Steel
02135	Small Inner Body Male Rotational Component		
02140	Small Locking Connector Bolt (4 pack)		Stainless Steel
02145	Small Inner Body Rotational Component Complete Includes:		Anodized Aluminum, Stainless Steel
02155	Small Dynamization Component (0-3cm)		Stainless Steel
02160	Small Dynamization Component (0-5cm)		



PS4340: Appendix A: External Fixation Devices – EBI DynaFix™ DFS™ Standard Fixator

Revision: NEW Effective: draft



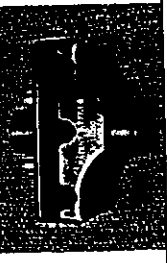
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02180	Small Modular C/D Mechanism (0-3cm) (replaces 02148)		Stainless Steel
02185	Small Modular C/D Mechanism (0-5cm) (replaces 02150)		
02200	DFS Small Convergent T-Clamp Offset		Anodized Aluminum, Stainless Steel
02250	DFS Small Convergent T-Clamp Parallel Includes: 02265, 02270, 02085	SAME AS ABOVE BUT WITH EVEN PIN DEPTH SLOTS	Anodized Aluminum, Stainless Steel
02255	Small Left Clamp Body		Anodized Aluminum, Stainless Steel
02260	Small Offset Clamp Body		Anodized Aluminum, Stainless Steel
02265	Small Parallel Clamp Body	SAME AS ABOVE BUT WITH SHALLOW PIN SLOTS	Anodized Aluminum, Stainless Steel
02270	Small Parallel Clamp Cover	 BOTTOM IS FLAT	Anodized Aluminum


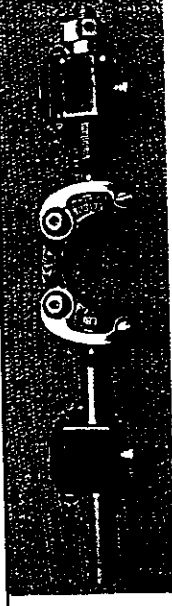
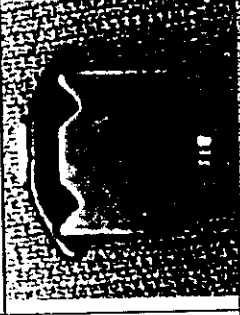
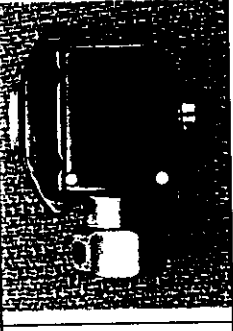
PS4340: Appendix A: External Fixation Devices – EBI DynaFix™ DFS™ Standard Fixator

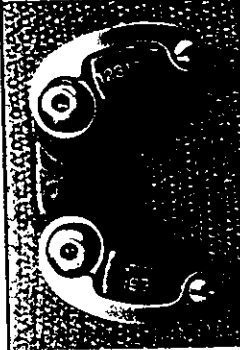
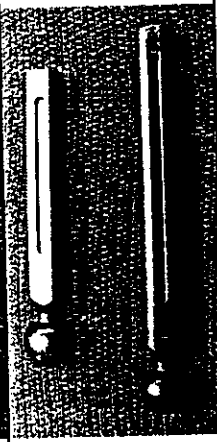





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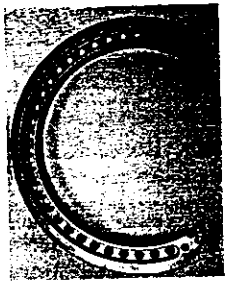




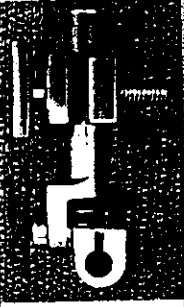


02275	Small Offset Clamp Cover			Anodized Aluminum
02320	Small 3-Hole T-Clamp Complete			Anodized Aluminum, Stainless Steel
02325	Small 3-Hole T-Clamp Body	SAME AS ABOVE BUT W/O TOP		Anodized Aluminum, Stainless Steel






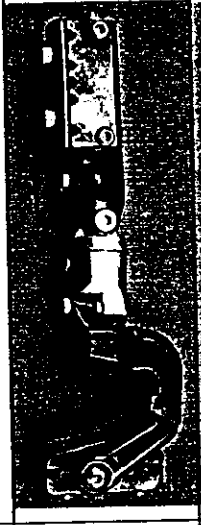
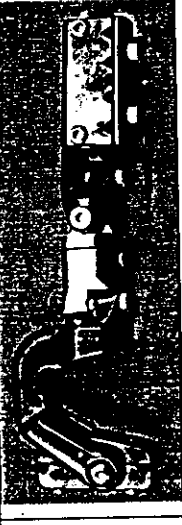
### DFS® (DRS) Distal Radius Fixator

04000	Distal Radius Fixator Complete Includes: Distal Radius Fixator (04001), 3mm T-Wrench (05045)	AS BELOW BUT WITH 3mm T-WRENCH ADDED AS KIT	Anodized Aluminum, Stainless Steel
04001	DFS Distal Radius Fixator Includes: Central Component (04005), Bone Screw Clamp (04025), Distal Fixator Rail (04010), Proximal Fixator Rail (04020)		Anodized Aluminum, Stainless Steel
04002	DFS Distal Radius Fixator with Distraction Module Complete Includes: Distal Radius Fixator w/Distraction Module (04003), 3mm T-Wrench (05045)	AS BELOW BUT WITH 3mm T-WRENCH ADDED AS KIT	Anodized Aluminum, Stainless Steel
04003	DFS Distal Radius Fixator with Distraction Module Includes: Central Component (04005), Bone Screw Clamp (04025), Bone Screw Clamp w/Distraction Module (04030), Distal Fixator Rail (04010), Proximal Fixator Rail (04020)		Anodized Aluminum, Stainless Steel
04025	Bone Screw Clamp		Anodized Aluminum, Stainless Steel
04030	Bone Screw Clamp with Distraction Module		Anodized Aluminum, Stainless Steel

04005	Central Component		Anodized Aluminum, Stainless Steel
04010	Distal Fixator Rail		Stainless Steel
04020	Proximal Fixator Rail		Stainless Steel
04050	Clamp Cover Locking Screw		Stainless Steel
04055	Fixator Rail Locking Screw		Stainless Steel
04056	Distraction Module Fixator Rail Locking Screw		Stainless Steel
04015	Collet Locking Screw (2 each)		Stainless Steel

## DFS® HYBRID FIXATOR (Misc. Accessories for STANDARD FIXATOR SYSTEM)

13005	130mm 1/3 Ring			Anodized Aluminum
13020	150mm 1/3 Ring			
13035	180mm 1/3 Ring			
13050	220mm 1/3 Ring			
13010	130mm 2/3 Ring			Anodized Aluminum
13025	150mm 2/3 Ring			
13040	180mm 2/3 Ring			
13055	220mm 2/3 Ring			
13060	Ring Locking Bolt (1/Pkg.)			Stainless Steel
13065	Ring to Fixator Connector			Anodized Aluminum, Stainless Steel
13070	Variable Wire Carriages (x6)			Anodized Aluminum, Stainless Steel
13080	Variable Bone Screw Carriage			Anodized Aluminum, Stainless Steel
13200	Left Ring Fixator Assembly			
13210	Right Ring Fixator Assembly			

14010	Rod-to-Rod Connector			Stainless Steel
14240	Vision Post			Stainless Steel
14060	Three Hole Clamp			Anodized Aluminum, Stainless Steel
14090	Five Hole Clamp			Carbon Fiber
14160	8mm Carbon Fiber Rod (Length 150mm)			
14165	Carbon Rod (9.5mm x 200mm)			
14170	9.5mm Carbon Rod (Length 250mm)			
14175	8mm Carbon Fiber Rod (Length 300mm)			
14180	8mm Carbon Fiber Rod (Length 340mm)			
14185	9.5mm Carbon Rod (Length 400mm)			Anodized Aluminum, Stainless Steel
90100	Left Ankle Kit			
90105	Right Ankle Kit			Anodized Aluminum, Stainless Steel

## Indications for Use

510(k) Number (if known):

K051616

Device Name: Vanguard Reprocessed External Fixation Devices

Indications for Use:

Reprocessed External Fixation Devices are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

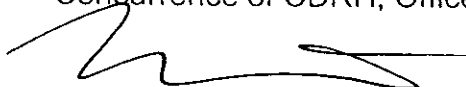
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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510(k) Number K051616